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10/524,674	02/14/2005	Hiroshi Nakayama	2005-0213A	8615

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EXAMINER

JUNG, UNSU

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/524,674

Applicant(s)

NAKAYAMA, HIROSHI

Examiner

Unsu Jung

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2006.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 and 48-60 is/are pending in the application.
 4a) Of the above claim(s) 1-33 and 48-60 is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 34-36 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 14 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.
 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) ☐ Notice of Informal Patent Application
 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendments to the specification in the reply filed on July 11, 2006 have been acknowledged and entered.
2. Applicant's amendments to cancel claims 37-47 and amend claims 34-36 in the reply filed on July 11, 2006 have been acknowledged and entered.
3. Claims 1-36 and 48-60 are pending and claims 34-36 are under consideration for their merits.

Objections Withdrawn

4. Applicant's arguments, see p16, filed on July 11, 2006, with respect to the objection of the drawings have been fully considered and are persuasive. The objection of the drawings has been withdrawn in light of amended specification in the reply filed on July 11, 2006.
5. Applicant's arguments, see p13, filed on July 11, 2006, with respect to the objection of claim 36 have been fully considered and are persuasive. The objection of claim 36 has been withdrawn in light of amended claim 36 in the reply filed on July 11, 2006.

Rejections Withdrawn

6. Applicant's arguments, see pp12-13, filed on July 11, 2006, with respect to the rejection under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The rejection of claims 34-47 under 35 U.S.C. 112, second paragraph has been withdrawn in light of amended claims 34-36 and cancelled claims 37-47 in the reply filed on July 11, 2006.

7. Applicant's arguments, see pp14-15, filed on July 11, 2006, with respect to the rejection under 35 U.S.C. 102(e) as being anticipated by Kopf-Sill et al. (U.S. Patent No. 6,524,790, Filed June 9, 1997) have been fully considered and are persuasive. The rejection of claims 34-39, 41-44, and 46 has been withdrawn in light of amended claim 34 and cancelled claims 37-39, 41-44, and 46 in the reply filed on July 11, 2006.

8. Applicant's arguments, see p16, filed on July 11, 2006, with respect to the rejection under 35 U.S.C. 103(a) as being unpatentable over Kopf-Sill et al. in view of Janjic et al. (U.S. Patent No. 6,329,145, Dec. 11, 2001) have been fully considered and are persuasive. The rejection of claims 40 and 45 has been withdrawn in light of cancelled claims 40 and 45 in the reply filed on July 11, 2006.

Specification

9. The use of the trademark CASCADE BLUE® (p45, line 15 and p46, lines 2 and 7) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant's amendments to the specification address the objection of the specification in the reply filed on July 11, 2006 has been acknowledged. However, the trademark CASCADE BLUE® in the specification as indicated above have not been capitalized. Therefore, the objection of the specification has been maintained.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1641

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopf-Sill et al. (U.S. Patent No. 6,524,790, Filed June 9, 1997) in view of Molnar et al. (*Biochemica et Biophysica Acta*, 1991, Vol. 1068, pp27-40) and Whitaker et al. (*Analytical Biochemistry*, 1991, Vol. 198, pp119-130).

Kopf-Sill et al. teaches a method of separating or quantitatively determining a target particle (analyte) in a sample, the method comprising the steps of:

- mixing a sample containing the target particle and a charge control agent such as an antibody or a nucleic acid, which specifically binds to the target particle (column 30, lines 31-52) and having a positive or negative charge in the sample (column 2, lines 36-50), and binding the charge control agent to the target particle (column 30, lines 31-52); and
- separating or quantitatively determining the target particle provided with the charge control agent bound thereto (column 1, lines 20-24), based on a surface charge modified by the binding of the charge control agent resulting from the mixing, by applying a voltage or current to the sample (column 30, lines 31-52).

Kopf-Sill et al. further that the target particle is selected from a group consisting of a bacterium, a virus, and a fungus (column 35, lines 13-23) and the charge control agent is a complex composed of an antibody, which is capable of specifically binding to the

Art Unit: 1641

biological functional substance and the marker bound to the antibody (column 7, lines 1-4). Kopf-Sill et al. teaches that a variety of binding agents (charge control agent) such as antibodies, proteins, receptor ligands, and nucleic acids (column 30, lines 31-52) labeled directly with fluorescent and colorimetric labels (column 27, line 64-column 8, line 37). However, Kopf-Sill et al. fails to teach a method, wherein the fluorescent label is an azido derivative of CASCADE BLUE[®], aminoethyl-4-azidebenzamide trisodium salt (ACB).

Molnar et al. teaches azido-derivatives of CASCADE BLUE[®], such as ACB (p30, Fig. 1). However, Molnar et al. fails to teach that ACB can be used to conjugate or label a charge control agent.

Whitaker et al. teaches that blue fluorescent dyes such as CASCADE BLUE[®] derivatives are suitable for a variety of biological, immunological and histochemical applications (p120, right column, lines 26-28). Specifically, CASCADE BLUE[®] derivatives can be conjugated with antibodies (pp123-124, *Indirect Immunofluorescence Staining*) in a detection assay with advantages of being readily soluble in aqueous preparations, insensitive to pH, minimally quenched on conjugation with macroscopic molecules and show low overlap with the emission spectra of commonly used green or yellow fluorescent dyes such as fluorescein and Lucifer Yellow (p120, right column, lines 4-15).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a blue fluorescent dyes such as ACB of Molnar et al. to label a charge control agent such as antibodies as taught by Whitaker et al. in the method of

Art Unit: 1641

Kopf-Sill et al. in order to detect a target particle in a immunological binding assays as CASCADE BLUE[®] derivatives has several advantages, which include being readily soluble in aqueous preparations, insensitive to pH, minimally quenched on conjugation with macroscopic molecules and show low overlap with the emission spectra of commonly used green or yellow fluorescent dyes. The properties of the dye having high solubility of the dye in aqueous solution would optimize the utility of the dye for modification of proteins and insensitive pH would be enable measured signal to be proportional to the absolute quantity of the dye present and not the pH of the solution during an assay.

With respect to claims 35 and 36, Kopf-Sill et al. teaches the method of claim 34, wherein the mixing step is separately performed for a plurality of types of particles with respective charge control agents, which are different from each other (column 26, lines 8-23).

Response to Arguments

13. Applicant's arguments filed on July 11, 2006 have been fully considered but they are not persuasive in view of previously stated grounds of rejection.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the label of Kopf-Sill is not used for giving charges to target particles) are not recited in the rejected claim(s). Although the claims are interpreted in light of the

Art Unit: 1641

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Since prior art fulfills all the limitations currently recited in the claims, the invention as currently recited would read upon the prior art.

Conclusion

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1641

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506.

The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Unsu Jung, Ph.D.
Patent Examiner
Art Unit 1641



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